

Appl. No. : 10/061,438  
Filed : January 31, 2002

### REMARKS

As discussed during the interview, Applicants have amended the claims. Support for these amendments will be discussed below.

#### Amendments to the Specification

Applicants respectfully request entry of the Amendment to the Specification set forth above to correct a minor typographical error. Paragraph 1 on page 10 replaces "branched-chair" with "branched-chain".

#### Amendments to Claims

As an initial matter, Applicants acknowledge the objection to the claims and the request of the Examiner in the last office action that the claims be renumbered on a going-forward basis to start with number 41, rather than number 35. Thus, the claims previously numbered as 35-48 have been renumbered herein as 41-54. It is believed that the Examiner did not want that change indicated as a formal amendment, and so no formal indication of that renumbering is reflected in the claim set itself.

Claims 41 and 52-54 have been amended. New Claim 55 has been added. Most of these amendments are word changes to clarify grammatical issues in response to the 35 USC §112, ¶2 rejections, raising no question of new matter. The phrase "independent of incubation time" that was added to Claim 41 is found in the specification at page 26, line 14. Claim 41 also specifies that the hydroxyboryl and negatively charged groups are immobilized, as indicated in the specification, e.g., at page 23, lines 27-29 in Example 1. The last phrase of Claim 41 has been canceled, and rewritten as new Claim 55.

#### The Indefiniteness Rejection, 35 USC The Indefiniteness Rejection, 35 USC §112, ¶2

The Examiner rejected Claim 41 under 35 U.S.C. § 112, ¶2 for reciting the pronoun "that" as in "that are capable of binding both the glycated" and as in "that are capable of binding the glycated form". Claim 41 has been amended to remove the pronoun "that" and to more precisely specify the term being modified. The Examiner rejected Claim 41 under § 112,

Appl. No. : 10/061,438  
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alleging that the identity of locations reference by "thereon" was unclear. Claim 41 has been amended clarify that "thereon" refers to "said support". The Examiner rejected Claim 41 under § 112, alleging that "to remove" was indefinite. Claim 41 has been amended to remove the infinitive and to specify changing the pH, "thereby removing both the nonglycated protein and the glycated protein". The Examiner rejected Claim 41 under § 112 on the ground that the use of the term "whereupon" was indefinite. Claim 41 has been amended to remove the term "whereupon" and replace it with "after which removal". The Examiner rejected Claim 52 on the ground that the duplication of the term "phenyl" was indefinite. Claim 52 has been amended to remove the duplicate term "phenyl". The Examiner rejected Claims 53 and 54 as indefinite. Claims 53 and 54 have been amended to use traditional Markush language, i.e., "selected from the group consisting of." Thus, each of the Examiner's § 112 ¶2 rejections has been addressed through the claim amendments discussed above.

Support in the Specification for the amendments to Claim 41 is found, for example, on page 17 ¶ 3; in Example 1 on page 24 ¶ 5; on page 26 Table 1 and ¶ 2 – page 27 ¶ 3; and Figure 3. Support for Claim 55 is found, for example, on page 13 ¶¶ 2, 3; page 15 ¶ 3; and page 16, lines 23-25 and in Example 1.

#### **Written Description Rejections Under 35 U.S.C. §112, ¶1**

Claim 41 was said to lack written description support for various recitations of "negatively charged group". As discussed in the interview, support for "negatively charged groups" is found, for example, in the specification at page 27, lines 11-14 and lines 17-20.

The PTO also questioned support for the phrase "without an incubation period" in Claim 41. This language has been replaced with "independent of incubation time" which is literally supported on page 26, line 14. It is intended that this phrase highlight the relatively rapid binding of the glycated protein to the hydroxyboryl groups, allowing the assay to proceed to an accurate conclusion regardless of whether or not one waits the amount of time required for such binding to take place in the prior art.

"Removing" non-glycated protein is supported in the specification, e.g., in Example 3 (pages 26-27) where pH is changed so that non-glycated protein no longer binds, and the wash/rinse step (e.g., page 6, lines 23-28 and page 29, lines 3-6).

Appl. No. : 10/061,438  
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The written description rejection of Claim 52 has been obviated by the addition of Markush terminology, as discussed above.

**Rejections Under 35 U.S.C. § 103(a)**

The pending claims were variously rejected over combinations of art that included Wu (U.S. Patent No. 5,985,121) in view of Murel (U.S. Patent No. 4,925,545). Both of these references relate to electrophoresis and isoelectric focusing. If these references were modified to bind mobile species, as required by the present claims (e.g., "binding both the glycosylated protein and the nonglycosylated protein" (Claim 41)), the resulting assay would be inoperable for its intended purpose, i.e., isoelectric focusing. It is axiomatic that a reference cannot be modified under Section 103 in such a way as to make it inoperable.

With regard to the obviousness rejection in light of U.S. Pat. No. 4,925,545 (*Murel*), Applicants point out that *Murel* teaches carboxyl derivatives for the purpose of "anchoring" groups to a solid support and therefore there is no "negatively charged group" capable of binding protein at the time the assay is performed, as recited in independent Claim 41.

*Murel* specifies that "the borate molecules and ions are mobile" (Col. 5, lines 41-43). In contrast, Claim 41 specifies that the hydroxyborate groups are "immobilized."

Further, Applicants note that none of the prior art cited by the Examiner recites a step of "performing a first measurement" indicative of glycosylated and non-glycosylated protein, followed by a binding step and a second measurement step.

For all of the foregoing reasons, a combination of the cited references would not result in the claimed invention. Thus, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Appl. No. : 10/061,438  
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### CONCLUSION

The Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action and enunciated in the interview. If any issues remain that could be resolved by telephone, the Examiner is invited to call the undersigned directly, in order to facilitate prompt and efficient allowance of this application. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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